

EPA Reg. No. 68451-1
Vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 14 2013

Ms Patricia Sheehy
Intervet, Inc.
D/B/A Merck Animal Health
556 Morris Avenue, S5-2145A
Summit, NJ 07901

Subject: Extension of the Deadline for Submission of Efficacy Data Required as a Condition of Registration

EPA Reg. No. 68451-1
Deltamethrin 4% Collar

Your request dated May 8, 2013

Dear Ms. Sheehy:

We considered your request for an extension of the deadline for submission of the data listed below, required as a condition of registration for the subject product under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Per your request, the deadline for submission of the subject data is extended to December 15, 2013.

Anti-feedant /Repellency for Mosquitoes (*Anopheles* sp. & *Aedes aegypti*), as specified on the Product Performance Data Evaluation Record (Sweeney, March 21, 2012) previously provided to you.

Please note that if these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

If you have any questions regarding this action, please contact Olga Odiott at (703) 308-9369.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", written over the word "Sincerely,".

Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Explore Registrations

Reg Number: 68451-1 Reg. Type: Product Registration - Section 3 Status: Conditionally Registered (05-Jun-13)
 Name: DELTAMETHRIN 4% COLLAR <View Registration Details>

(No New Receipts)

Submission Type	OPP Rec'd Date	Resubmission	Description

- ...Decisions...
- D: Pending; 478768; 68451-1,350; GENERAL CC
 - 75-Day Letters
 - 478768; 350; GENERAL CORRESPONDENCE
 - D: Closed; 457072; 68451-1,330; NON-FAST-7
 - D: Closed; 429737; 68451-1,332; NOTIFICATION
 - D: Closed; 427000; 68451-1,332; NOTIFICATION
 - D: Closed; 426587; 68451-1,332; NOTIFICATION
 - D: Closed; 415181; 68451-1,332; NOTIFICATION
 - D: Closed; 144305; 68451-1,300; LABEL REVISION
 - D: Closed; 144304; 68451-1,360; ACTION INITIA
 - D: Closed; 144303; 68451-1,305; DATA REQUIR.
 - D: Pending; 144302; 68451-1,305; DATA REQUIR.
 - D: Closed; 144301; 68451-1,360; ACTION INITIA
 - D: Pending; 144300; 68451-1,570; CONDITIONA
 - D: Closed; 144299; 68451-1,165; NEW REGISTR
 - Data Requirements

ALERT S: 335504 Reg # 68451-1

Submission Type: Miscellaneous Receipt

Resubmission?: ☐ Yes ☒ No E Sub #:

Decision #: 478768; 350; GENERAL CORRESPONDENCE;

Submitter Company: INTERVET INC

Application Date: 08-May-2013

OPP Received Date: 08-May-2013

Date Sent to Risk manager: 08-May-2013

Studies Included?: ☐ Yes ☒ No

Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Odiott, Olga

Received DT: 08-May-2013

Editable Due DT:

Submission Due DT: 26-Aug-2013

Response: 0, 08-May-2013

Priority Weight:

Priority Points:

Comments: Time extension request

00:75 Day

00:75 Day

Odiott, Olga

From: Sheehy, Patricia [patricia.sheehy@merck.com]
Sent: Wednesday, May 08, 2013 2:48 PM
To: Odiott, Olga
Subject: Extension Request for Submission of data to support Mosquito Claim
Attachments: EPA Approval Letter March 21 2012.pdf; Amblyomma -Mosquitoes REVIEW March 2012.pdf

Ms. Odiott:

I am so sorry we keep missing each other on the phone. As I mentioned in my voice mail on Tuesday May 7th, EPA found our mosquito claims acceptable for our Deltamethrin 4% Collar provided we agreed to submit additional data with the mosquito Genus Aedes (using *Ae. aegypti* as the test species) and the mosquito Genus Anopheles (suggest *Anopheles quadrimaculatus* as the test species but other species may be justified). This was written up in the March 2012 DER.

We started working with outside contract labs last summer but due to space and scheduling with the labs and the inability to obtain the required mosquito genus during the fall and winter months – we have only just been able to initiate the required work.

At this time I would like to request EPA approval of an extension from the March 2013 due date to Dec. 15, 2013. We have a contract signed with a laboratory and a schedule of the study that confirms I will have the final report on or before the Dec. 15 2013 date requested.

Attached is a copy of the EPA letter and DER to which I am referring. We did not have the cover letter when we starting looking at labs last summer and it was just now brought to my attention that while the DER was not specific about a deadline the cover letter identified the March 2013 due date.

I am hopeful that EPA can approve this request. I will be in the office through Thursday May 9th if you need any further information. I will be out of the office on vacation returning Monday May 20th.

With kind regards

Trish

Regulatory Affairs

T: (908) 473-3551

F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAR 21 2012

Ms. Heather R. Bjornson
Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036

Subject: Label Amendment to Add Efficacy Claims

EPA Reg. No. 68451-1
Deltamethrin 4% Collar

Your Submission Dated October 31, 2012

Dear Ms. Bjornson;

The labeling referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below.

1. The mosquito claims are acceptable provided you agree to submit additional data (Guideline 810.3400), as specified on the enclosed Efficacy Review Memo (Sweeney, March 21, 2012). Such data should be submitted to the Agency by March 2013, one year from the date of this Memo.
2. Repellency claims for ticks are not acceptable based on the submitted data, therefore, delete the claims throughout the label.

Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of the label is enclosed for your records. Two (2) copies of the final printed labeling must be submitted prior to releasing the product for shipment.

If you have questions regarding this action, please contact Olga Odiott at (703) 308-9369.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", is written over the typed name.

Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosure



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WASHINGTON, D.C. 20460

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Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of the label is enclosed for your records. Two (2) copies of the final printed labeling must be submitted prior to releasing the product for shipment.

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Sincerely,

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Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosure

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACCEPTED
with COMMENTS
in EPA Letter Dated
MAR 21 2012
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
68451-1

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Intervet Inc (d/b/a Merck Animal Health)
Summit, NJ 07901

Product of France

SCALIBOR®
FLEA & TICK COLLAR
FOR DOGS
DELTAMETHRIN 4%
NET WT. 0.9 oz
EPA REG. NO. 68451-1

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 -- 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 -- 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
<p>For incidents involving HUMANS, call 1-800-680-9206</p> <p>For incidents involving ANIMALS, call 1-800-224-53181 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment</p>	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

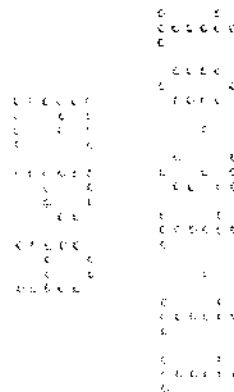
Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France



Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (*Ctenocephalides* sp.) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill and repel ticks for up to 6 months including: Lone Star tick (*Amblyomma americanum*), Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI))

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosis.¹

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis; s

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Protects against mosquito bites for up to six months.

11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Olga Odiott

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in black ink, appearing to read "Kevin Sweeney", with a long, sweeping checkmark-like stroke extending from the end.

Date: March 21, 2012

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 396235

Decision no.: 457072

Submission no: 906189

Action code: R340

Product Name: Deltamethrin 4% Collar

EPA Reg. No or File Symbol: 68451-1

Formulation Type: RTU dog collar

Ingredients statement from the label with PC codes included: 4% deltamethrin (w/w) (PC code: 097805)

Use pattern: dog collar for use against fleas, ticks and mosquitoes

Application rates of product/active ingredient: RTU dog collar with claims of 6 months longevity

OCSPP Guideline 810.3300

I. Action Requested: Review two studies and the new product label. Registrant requests the addition of the Lone star tick to the label and mosquito claims.

II. Background: The subject product is a registered dog collar. The registrant submitted two MRIDs in support of the subject amendment. One study evaluated the repellency and kill efficacy of the collar against Lone star ticks and fleas. The second study assessed the anti-feedant properties against one adult mosquito species, *Culex pipiens pipiens*.

III. Study reviews:

1. MRID 48646602 Hair, J.A. 2011. Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (*Amblyomma americanum*) and Flea (*Ctenocephalides felis*) on Dogs.

This study was done in accordance with GLP except that fed and water sample testing for pesticides was not done according to GLP and the testing facility did not have the staff to oversee the work of the study director because it was a small business.

Purpose: To assess the subject product for: 1) kill efficacy of the against Lone Star ticks and fleas; and 2) the repellent activity against Lone Star ticks.

Materials and Methods:

Study location: Nu-Era Farms, 320 N. Range Road, Stillwater, OK 74075

Test substance: Scalibor collar - 4% (w/w) deltamethrin

Control substance: untreated placebo collar

Test companion animals: Beagle breed dogs from Nu-Farm dog colony. The 22 dogs used in the study consisted of 11 males and 11 females. Based on pre-study to evaluate tick infestation, 20 dogs were selected – 10 males and 10 females. All dogs had short-hair and ranged in age from 4-7 years. During infestation each animal was housed in its own cage.

Test conditions: 62-97° F

Test species: Adult life stage of the Lone Star tick, *Amblyomma americanum*, and cat flea (*Ctenocephalides felis*). Study director presumed a sex ratio of 1:1 for the ticks.

Tick study experimental design: randomized complete block design with pre-treatment counts as a blocking factor. The experimental unit (replicate) was a dog and there were two treatments (n = 10 for each): a 4% deltamethrin dog collar treatment and untreated placebo control treatment. Twenty-two dogs were screened for attractiveness to Lone Star ticks and the 20 most attractive dogs were used in the study. There were ten randomly assigned blocks of two dogs each and the treated dog in each block was also assigned at random.

Tick repellency evaluation: Dogs were exposed to 50 free ranging ticks placed in the chamber with them for two hours. Tick repellency was evaluated on days 23, 75, 13 and 187 post-treatment. Repellency was evaluated for up to 48 hours post-exposure.

Tick efficacy evaluation: 50 ticks were placed in the chamber. Dogs were exposed to ticks in the infestation chamber for 4 hours on days 14, 28, 56, 89, 118, 147 and 180. Efficacy was evaluated at the end of a 48 hour period on days 16, 30, 58, 91, 120, 149 and 182.

For ticks, at least 25% of ticks had to attach to the control animals for the control and treated

results to be considered.

Flea experimental design: randomized complete block design with pre-treatment counts as a blocking factor. The experimental unit was a dog and there were two treatments (n = 10 for each): a 4% deltamethrin dog collar treatment and untreated placebo control treatment.

Flea efficacy evaluation: Dogs were infested with 100 newly emerged unfed fleas each on days 15, 29, 57, 90, 119, 148 and 181. Efficacy was evaluated over a 24 hour period on days 16, 30, 58, 91, 120, 149 and 182.

Data points reported:

- Tick efficacy: number of live ticks found on dogs at 48 hours post tick exposure.
- Tick repellency: number of ticks recovered in the cage (live and dead) plus number of unattached tick dead ticks on the dog.
- Flea efficacy: number of live fleas recovered from each dog at 24 hours post flea exposure.

Data analysis: data were log transformed. A mixed linear model with repeated measures was used to analyze the data. The repeated measures were treatment, day, and treatment*day as fixed effects with block and block*treatment as random effects. Least square means were used for means comparisons and back transformed to obtain geometric means. A Kenward-Roger's adjustment was used to determine the denominator degree of freedom for hypothesis. Akaike's Information Criterion (AIC) was used as the criterion to select the covariance structure for repeated measures. SAS 9.1.3 was used. The level of significance was $p \leq 0.05$

Major deviations: There were 4 amendments listed in the study and three deviations. In addition, dog collar attachment was reported in the results but collar replacement not listed as a deviation from the protocol. Dog collars were removed and replaced on many treated and untreated dogs due to irritation or breakage from trying to scratch them off. The study does not discuss the effect of these changes on study results or longevity of efficacy. The dates of collar change were not reported. Per the Agency's request, Intervet has agreed to amend the study to discuss this issue. The registrant explained by personal communication that in nearly every case the same collar was used as a replacement and that the collar replacement did not impact study results.

Results:

Following tick infestations, not all ticks were recovered at the end of the exposure and evaluation periods. The tick attachment rate in the study for the untreated control dogs ranged from 31-40%.

Tick efficacy:

- Untreated control dogs had infestation rates of 28-54%. This translated into a mean of 14-28 ticks per dog from the 50 ticks used to infest the chamber.

- Tick kill on dogs was 98.5% or higher through 6 months

Flea efficacy:

- Untreated control dogs had infestation rates of 62-72%. This translated into a mean of 62-72 fleas per dog.
- Flea kill on dogs was 99% through 6 months.

Tick repellency:

- Repellency was 80% or less during the course of the study.

Conclusions: The study is acceptable. The results support a six month kill claim against fleas and the Lone Star tick. The study does not support a repellency claim against ticks.

Comments on study conduct:

- Collar replacement should be better documented and the effects on study results described. This should also be reported as a deviation from the protocol.
- Live crawling ticks and attached ticks (live or dead) should be considered as not repelled. Unattached dead ticks or ticks not on the animal but recovered in the cage may be considered as repelled. EPA believes that any tick attached to a dog is not repelled.

2. MRID 48646601 Franc, M. 2004. A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% w/w deltamethrin) on Adult Female Mosquitoes *Culex pipiens pipiens* on Dogs. (Nat. Veterinary School, Toulouse, France)

This is not a GLP study but conforms to Good Clinical Practice (GCP).

Purpose: To assess the anti-feedant effects of a 4% deltamethrin dog collar (Scalibor) against *Cx. pipiens pipiens* mosquitoes.

Materials and Methods

Study location: National Veterinary School, Dept. of Public Health, Dermatatology-Parasitology, Toulouse, France

Test substance: Scalibor collar- 4% (w/w) deltamethrin

Untreated control: No collar appeared to be used.

Test companion animals: Beagle dogs. The 20 dogs used in the study consisted of 8 males and 12 females. Based on a pre-study to evaluate attractiveness to mosquitoes, the dogs were ranked in order of attraction. All dogs had short-hair and ranged in age from 3-4 years. During

mosquito exposure each animal was sedated and placed in a room by itself. Treated and control animals were placed in separate rooms during mosquito evaluations.

Test conditions: “environmentally controlled” with temperature, relative humidity and photoperiod not reported in the study but retained on the raw data sheets.

Test species: Adult *Cx. pipiens pipiens* mosquitoes that were 1-4 weeks old. Mosquitoes were not fed for at least 48 hours before exposure to dogs. The mosquito strain used was susceptible to deltamethrin and adapted to feeding on dogs since this mosquito species usually prefers birds.

Experimental design: Randomized design and dogs were paired with another dog of equal susceptibility to mosquitoes and assigned to treatments as described in the study (Sec 6.2 on page 7 of 19). Testing was done in two parts, each with 4 treated, 4 untreated and 2 reserve dogs (one treated and one untreated) in each study part. Dogs were sedated during testing, placed in a mosquito net structure in the room and exposed to 50 female mosquitoes for 1.5 hours. Dogs were removed at the end of this time. After the dogs were removed, the mosquitoes were fed sugar or honey water through 48 hours post-exposure. Mortality and blood feeding status were assessed at 18-24 hours and at 48 hours exposure.

Data were pooled from replicates in each treatment. Data points reported included: 1) live and engorged mosquitoes; 2) live and unengorged; 3) dead and engorged; and 4) dead and unengorged. The study was conducted for 27 weeks. Data points were reported from weekly exposure intervals at weeks 1, 24, 9, 13, 16, 20, 25, and 27.

Data analysis: The four data points were calculated for treated and untreated data. Treatment and category means were compared.

Results:

- Over 99% of the mosquitoes did not feed on the treated dogs.
- The deltamethrin treatments did result in mortality values of over 60% in the treatments for most of the study weeks. However, dead mosquitoes were not engorged.
- Untreated control mortality was 2% or less throughout the study.

Conclusion: The study is acceptable. The results show that the 4% deltamethrin collar reduced feeding by mosquitoes exposed to treated dogs and supports anti-feedant and repellency claims. Data was only submitted for one mosquito species and conditional data should be required for *Aedes aegypti* and an *Anopheles* sp. mosquitoes.

IV. Entomologist's Recommendations:

1. The studies are acceptable. The registrant will amend MRID 48646602 to fully document collar replacements and the lack of effect on study results.
2. The addition of the Lone Star tick and associated kill claims to the label are acceptable.
3. Tick repellency claims are not acceptable based on the data submitted for the Lone Star tick.
4. The mosquito claims listed on the label are acceptable provided the registrant agrees to conduct a study with the mosquito Genus *Aedes*, (using *Ae. aegypti* as the test species), and the mosquito Genus *Anopheles*, (suggest *Anopheles quadrimaculatus* as the test species but other species may be proposed and justified.)
5. The remaining label claims presented in this amendment together with past claims added by notification are acceptable.

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

Intervet Inc (d/b/a Merck Animal Health)
Summit, NJ 07901

Product of France

NET CONTENTS: 1 Collar
NET WT. 0.9oz

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
<p>For incidents involving HUMANS, call 1-800-680-9206 For incidents involving ANIMALS, call 1-800-224-53181 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735. Have the product container or label with you when calling a poison control center or doctor, or going for treatment</p>	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

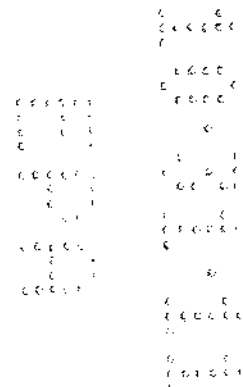
Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France



OPTIONAL/ALTERNATE LABEL TEXT

No Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (*Ctenocephalides sp.*) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill and repel ticks for up to 6 months including: Lone Star tick (*Amblyomma americanum*), Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI))

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Protects against mosquito bites for up to six months.

[illegible]



Summary of Discussion/March 19 2012/Deltamethrin Collar Efficacy Study
Sheehy, Patricia

to:

Kevin Sweeney

03/20/2012 04:45 PM

Cc:

"Heather Bjornson (HBjornson@TSGUSA.COM)"

Hide Details

From: "Sheehy, Patricia" <patricia.sheehy@merck.com>

To: Kevin Sweeney/DC/USEPA/US@EPA

Cc: "Heather Bjornson (HBjornson@TSGUSA.COM)" <HBjornson@TSGUSA.COM>

Mr. Sweeney:

My apologies for getting this out to you so late today but as promised I am sending this communication to confirm our discussion yesterday with regard to our efficacy submission for our Deltamethrin Collar, EPA Reg No 68451-1 (Ref. MRID48646602): Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (*Amblyomma americanum*) and Flea (*Ctenocephalides felis*) Infestations in Dogs.

Your March 19, 2012 email to Heather Bjornson indicated the following:

In this study, the director reported the reapplication of dog collars to the test animals (page 24). The study was conducted for 6 months but as described in Table 5 (Page 29) only two treated dogs wore the original collar throughout the study. The rest of the treated dogs had collars replaced from 2-4 times.

In table 5, the weight of the replaced collar (including residual pieces for fitting) is deducted from the weight of the original collar and expressed as applied weight? Collars used as replacements were not aged. Therefore, there is some kind of assumption, which I don't understand, that the collars will release deltamethrin at the same rate every day of the study. This seems unlikely at best because the temperature during the in-life phase of the study varied by as much as 30 degrees F. Release rate from the collars and tick flea activity is likely to be affected by ambient temperature. The temp was not the same in the study and it should have been.

Older Deltamethrin studies, previously reviewed by the Agency, have supported the 6-month efficacy duration of this collar. The reason the collars were removed and replaced on the dogs is that these dogs were not used to having collars on and as a result after initial application, tended to scratch the area so frequently some dogs the collars came off their necks. In most cases the same collar was put back on the dog but in a few cases the dogs actually broke the clasp and the collars had to be replaced.

Taking into consideration what we know about the slow release of the material from the collar, equilibrium of the deltamethrin over the dogs body is maintained even if a new collar is applied. Previous studies on release of the material show that release rate is dependent upon friction and environmental conditions.

These dogs were kept in an indoor barn with fans and was designed more to ensure field conditions. The collars were not aged. Again the release of material and spread over the dog's entire body being based on the amount of friction and amount of material released and necessary to ensure equilibrium. As the material gets washed off, additional material is released from the collar. Our assumption is not that the same amount of deltamethrin is released at the same rate every day but rather deltamethrin is released as needed on a daily basis and can differ from dog to dog.

I agree that our final study report could have provided more detail in addressing your questions. It is our intention to provide an amended report to EPA to ensure that clarification is provided and is documented to the points we discussed yesterday.

Please let me know if you need any further clarification

With kind regards

Trish

Regulatory Affairs

T: (908) 473-3551

F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

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DATA PACKAGE BEAN SHEET

Date: 17-Nov-2011

Page 1 of 2

Decision #: 457072

DP #: (396235)

PRIA

Parent DP #:

Submission #: 906189

E-Sub #:

*** Registration Information ***

Registration: 68451-1 - DELTAMETHRIN 4% COLLAR

Company: 68451 - INTERVET INC

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Olga Odiott OODIOTT

Sent Date: _____

Calculated Due Date: 22-Mar-2012

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R340) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEME

Ingredients: 097805, Deltamethrin(4%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 17-Nov-2011

Due Back: _____

DP Ingredient: 097805, Deltamethrin

DP Title: _____

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 21-Feb-2012

Team Name: Efficacy (IB)

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attached for your review dat submitted to support adding label claims of efficacy for up to 6 months.

MRID	MRID Status	Citation Reference	Guideline	OC-5 Status
48646601		Franc, M. (2004) A Pivotal Clinical Study to Assess the Anti-feeding Effect of Scalibor Protector Band (4% W/W Deltamethrin), on Adult Female Mosquitoes <i>Culex pipiens</i> , on Dogs. Project Number: V/0193/0772. Unpublished study prepared by National Veterinary Institute. 79p.	810.3300/Treatments to control pests of humans and pets	
48646602		Hair, J. (2011) Efficacy and Repellency of Scalibor Collar for the Prevention of Tick (<i>Amblyomma americanum</i>) and Flea (<i>Ctenocephalides felis</i>) Infestations on Dogs. Project Number: N10/032/01. Unpublished study prepared by Nu-Era Research Farms. 72p.	810.3300/Treatments to control pests of humans and pets	

Viewing Record 1 of 1

Memorandum

Date: 11 / 08 / 11

To: PM 13, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 10-31-11

Experts In-Processing Signature: MF HARRINGTON Date 11-1-11

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>68451-1</u>		EPA Receipt Date: <u>10-31-11</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)				X
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X		
	a) Selective Method (Fee category experts use)	yes	no		
	b) Cite-All (Fee category experts use)	X			
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

CC
1-8-11
Comments:

- 86.5: Associated studies have passed 86.5 review.
- Inerts: No inerts to review.
- Documentation: Pass

Pass

MRID 486466

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opppbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 07, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

INTERVET INC
556 MORRIS AVENUE, S5-2145A
SUMMIT, NJ 07901

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-NOV-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 906169

Registration: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment


Billable: ☒ Yes ☐ No


Company: 68451 INTERVET INC V


Risk Manager: Registration Division, Risk Management Team 13

Product #: 68451-1 Product Name: DELTAMETHRIN 4% COLLAR

Me Too Section 3: Me Too Product Name:

Application Date: 01-Oct-2011 

OPP Rec'd Date: 01-Nov-2011 

Front End Date: 01-Nov-2011 

Risk Manager Send Date: 

FPS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Information: ☐

Receipt Description:

Label amendment requiring Data

Resubmission: ☐
Resubmit Date:
Resubmit Date:
Resubmit Date:
Resubmit Date:

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Study	
Paper Label	

View/Edit



Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Direct: (202) 828-8945
Fax: (202) 872-0745
E-Mail: hbjornson@tsgusa.com

Heather R. Bjornson
Senior Regulatory Consultant

October 31, 2011

Mark Suarez
Registration Division, PM 13
Office of Pesticide Products, US EPA
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

PRIA Category R340 - Amendment Requiring Data

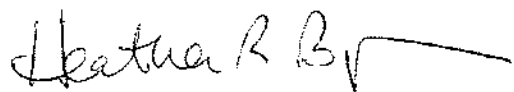
Dear Mr. Suarez:

Technology Sciences Group Inc., on behalf of Intervet, Inc., is submitting the enclosed amendment to add additional claims for the product being efficacious for up to 6 months. Along with this amendment, data is being submitted to substantiate these new claims. You will find the following included to support this amendment:

1. Amendment application form,
2. Certification with respect to data citation,
3. Data matrix (confidential and non-confidential versions),
4. One copy of the proposed label (highlighted),
5. Three copies of the revised clean label,
6. Data Volumes 1 through 3 (refer to the transmittal document for additional information), and
7. PRIA pre-payment receipt – Pay.gov tracking ID: 254Q0ASI; Agency Tracking ID: 74249677715.

Should you have any questions or comments, please do not hesitate to contact me directly.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather R. Bjornson", followed by a horizontal line.

Heather R. Bjornson

VOLUME 1 of 3

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Intervet Inc D/B/A Merck Animal Health
556 Morris Avenue , S5-2145A
Summit, New Jersey 07901

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application for a Label Amendment with Data
PRIA Category: R340
Product Name: Deltamethrin 4% Collar, EPA Reg. No: 68451-1

3. TRANSMITTAL DATE

October 31, 2011

4. LIST OF SUBMITTED DOCUMENTS (3 copies of each volume)

VOLUME 1 Transmittal Document

48646601 VOLUME 2 A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% Deltamethrin), On Adult Feeding Mosquitoes *Culex Pipiens*, On Dogs. Study No. V-0193-0772
Guideline 810.3300

48646602 VOLUME 3 Efficacy and Repellency of Scalibor® Collar for the Prevention of Tick (*Amblyomma americanum*) and Flea (*Ctenocephalides felis*) infestations on Dogs Study Number: N10-032-01
Guideline 810.3300.

5. COMPANY NAME: Intervet Inc. D/B/A Merck Animal Health
556 Morris Avenue, S5-2145A
Summit, New Jersey 07901

6. COMPANY OFFICIAL: Heather R. Bjornson
Senior Regulatory Consultant

7. SIGNATURE





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 1, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-457072
EPA File Symbol or Registration Number: 68451-1
Product Name: DELTAMETHRIN 4% COLLAR
EPA Receipt Date: 01-Nov-2011
EPA Company Number: 68451
Company Name: INTERVET INC

PATRICIA A. SHEEHY
INTERVET INC
D/B/A MERCK ANIMAL HEALTH
556 MORRIS AVENUE, S5-2145A
SUMMIT, NJ 07901-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "W. J. B.", is written over the typed name.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{906189Q~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S- 906189

EPA File Symbol/Reg. No.

68451-1

Pin-Punch Date:

10/31/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

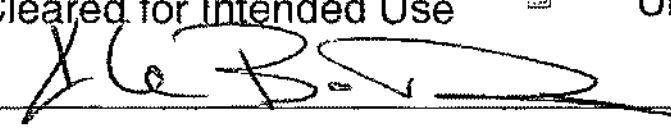
Granted: R340

Amount Due: \$ ~~40,000.00~~
3,617.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 11-1-11

Remarks:

Receipt for Section 3

S: 806189

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 88451 INTERVET INC

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 88451-1 Product Name: DELTAMETHRIN 4% COLLAR

On Hold #:

Me Too
Section3:

Me Too
Product Name:

Application Date: 31-Oct-2011

ie

OPP Rec'd Date: 01-Nov-2011

ie

Front End Date: 01-Nov-2011

ie

Risk Manager Send Date:

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Track Track:

New Information:

Receipt Description:

Label amendment requiring Data

Not in Report

Request Date:

New in Report

Refined Date:

Signatures:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

Heather Bjornson

From: paygovadmin@mail.doc.twai.gov
Sent: Thursday, October 27, 2011 11:28 AM
To: Heather Bjornson
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 254Q0ASI
Agency Tracking ID: 74249677715
Transaction Type: Sale
Transaction Date: Oct 27, 2011 11:27:45 AM

Account Holder Name: Heather R. Bjornson Transaction Amount: \$3,617.00 Billing Address: 1150 18th Street, NW Billing
Address 2: Ste. 1000
City: Washington
State/Province: DC
Zip/Postal Code: 20036
Country: USA
Card Type: AmericanExpress
Card Number: *****1436

Decision Number:
Registration Number: 68451-1
Company Name: Intervet Inc. D/B/A Merck
Company Number: 68451
Action Code: R340

11/27/2011 11:28 AM
Pay.gov Payment Confirmation
Transaction ID: 254Q0ASI
Agency Tracking ID: 74249677715
Transaction Type: Sale
Transaction Date: Oct 27, 2011 11:27:45 AM
Account Holder Name: Heather R. Bjornson
Transaction Amount: \$3,617.00
Billing Address: 1150 18th Street, NW
Billing Address 2: Ste. 1000
City: Washington
State/Province: DC
Zip/Postal Code: 20036
Country: USA
Card Type: AmericanExpress
Card Number: *****1436
Decision Number:
Registration Number: 68451-1
Company Name: Intervet Inc. D/B/A Merck
Company Number: 68451
Action Code: R340



Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Direct: (202) 828-8945
Fax: (202) 872-0745
E-Mail: hbjornson@tsgusa.com

Heather R. Bjornson
Senior Regulatory Consultant

October 31, 2011

Mark Suarez
Registration Division, PM 13
Office of Pesticide Products, US EPA
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

PRIA Category R340 - Amendment Requiring Data

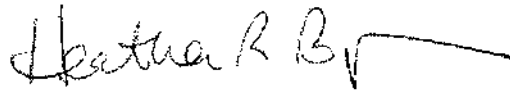
Dear Mr. Suarez:

Technology Sciences Group Inc., on behalf of Intervet, Inc., is submitting the enclosed amendment to add additional claims for the product being efficacious for up to 6 months. Along with this amendment, data is being submitted to substantiate these new claims. You will find the following included to support this amendment:

1. Amendment application form,
2. Certification with respect to data citation,
3. Data matrix (confidential and non-confidential versions),
4. One copy of the proposed label (highlighted),
5. Three copies of the revised clean label,
6. Data Volumes 1 through 3 (refer to the transmittal document for additional information), and
7. PRIA pre-payment receipt – Pay.gov tracking ID: 254Q0ASI; Agency Tracking ID: 74249677715.

Should you have any questions or comments, please do not hesitate to contact me directly.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather R. Bjornson", followed by a horizontal line extending to the right.

Heather R. Bjornson

VOLUME 1 of 3

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Intervet Inc D/B/A Merck Animal Health
556 Morris Avenue , S5-2145A
Summit, New Jersey 07901

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application for a Label Amendment with Data
PRIA Category: R340
Product Name: Deltamethrin 4% Collar, EPA Reg. No: 68451-1

3. TRANSMITTAL DATE

October 31, 2011

4. LIST OF SUBMITTED DOCUMENTS (3 copies of each volume)

VOLUME 1 Transmittal Document

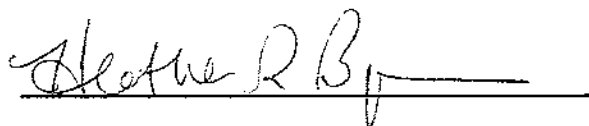
48646601 VOLUME 2 A Pivotal Clinical Study to Assess the Anti-Feeding Effect of Scalibor Protector Band (4% Deltamethrin), On Adult Feeding Mosquitoes *Culex Pipiens*, On Dogs. Study No. V-0193-0772
Guideline 810.3300

48646602 VOLUME 3 Efficacy and Repellency of Scalibor® Collar for the Prevention of Tick (*Amblyomma americanum*) and Flea (*Ctenocephalides felis*) infestations on Dogs Study Number: N10-032-01
Guideline 810.3300.

5. COMPANY NAME: Intervet Inc. D/B/A Merck Animal Health
556 Morris Avenue, S5-2145A
Summit, New Jersey 07901

6. COMPANY OFFICIAL: Heather R. Bjornson
Senior Regulatory Consultant

7. SIGNATURE





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet, Inc. D/B/A Merck Animal Health 556 Morris Avenue Summit, NJ 07901 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

PRIA Category R340: Label amendment requiring data. Please confirm with Heather Bjornson via e-mail: hbjornson@tsgusa.com.

PRIA pre-payment: Pay.gov Tracking ID: 254Q0ASI; Agency Tracking ID: 74249677715.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input checked="" type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 collar, 0.9 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Intervet, Inc.	
4. Typed Name Heather R. Bjornson	5. Date October 31, 2011	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Intervet, Inc D/B/A Merck Animal Health, 556 Morris Ave, Summit NJ 07901 / (908) 473-3551	EPA Registration Number/File Symbol 68451-1
Active Ingredient(s) and/or representative test compound(s) Deltamethrin	Date October 31, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) INDOOR	Product Name Deltamethrin 4% Collar

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

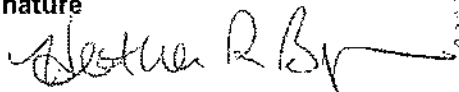
Signature 	Date 10/31/2011	Typed or Printed Name and Title Heather R. Bjornson, Sr. Regulatory Consultant
---------------	--------------------	---

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

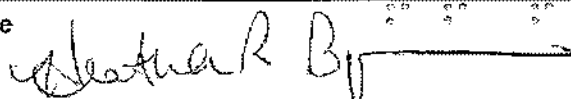
Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-1		Page 1 of 3
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit, New Jersey 07901			Product Deltamethrin 4% Collar		
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	42893501	Bayer Environmental Science	PER	
830-1600	Beginning materials	42893501	Bayer Environmental Science	PER	
830-1650	Description of formulation process	42893501	Bayer Environmental Science	PER	
830-1670	Formation of impurities	42893501	Bayer Environmental Science	PER	
830-1750	Certified limits	42893502	Bayer Environmental Science	PER	
830-1800	Enforcement analytical method	42893502	Bayer Environmental Science	PER	
830-6302	Color	42893503	Bayer Environmental Science	PER	
830-6303	Physical state	42893503	Bayer Environmental Science	PER	
830-6304	Odor	42893503	Bayer Environmental Science	PER	
830-6314	Oxidation/Reduction		End use product does not contain an oxidizing or reducing agent.		
830-6315	Flammability	42893503	Bayer Environmental Science	PER	
830-6316	Explosibility		End use product is not potentially explosive.		
830-6317	Storage stability	42893503	Bayer Environmental Science	PER	
830-6319	Miscibility		End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Patricia A. Sheehy Manager, Regulatory Affairs		Date October 31, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-1		Page 2 of 3
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit, New Jersey 07901			Product: Deltamethrin 4% Collar		
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	42893503	Bayer Environmental Science	PER	in progress
830-6321	Dielectric breakdown voltage		End use product is not to be used around electrical equipment.		
830-7000	pH		End use product is not to be dispersed with water.		
830-7100	Viscosity	42893503	Bayer Environmental Science	PER	
830-7300	Density	42893503	Bayer Environmental Science	PER	
870-1100	Acute oral toxicity	42889001	Bayer Environmental Science	PER	
870-1200	Acute dermal toxicity	42889002	Bayer Environmental Science	PER	
870-1300	Acute inhalation toxicity				Waiver Request
870-2400	Primary eye irritation-rabbits	42889003	Bayer Environmental Science	PER	
870-2500	Primary dermal irritation-rabbits	42889004	Bayer Environmental Science	PER	
870-2600	Skin sensitization	42889005	Bayer Environmental Science	PER	
810.3300	Product performance, efficacy	44190101	Intervet Inc.	Own	Submitted 12/26/1996
810.3300	Product performance, efficacy	44578701, 44578702, 44578703, 44578704, 44578705	Intervet Inc.	Own	Submitted 6/10/1998
Signature 			Name and Title Patricia A. Sheehy, Manager, Regulatory Affairs		Date October 31, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-1		Page 3 of 3
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit, New Jersey 07901			Product: Deltamethrin 4% Collar		
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Product performance, efficacy	44602901	Intervet Inc.	Own	Submitted 6/10/1998
870.7200	Domestic Animal Safety (dogs)	42889006	Bayer Environmental Science	PER	
810.3300	Product performance, efficacy	This submission	Intervet Inc.	Own	
Signature <i>Patricia A. Sheehy</i>			Name and Title Patricia A. Sheehy, Manager, Regulatory Affairs		Date October 31, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 31, 2011		EPA Reg. No./File Symbol: 68451-1		Page 1 of 3	
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit, New Jersey 07901		Product Deltamethrin 4% Collar			
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			End use product does not contain an oxidizing or reducing agent.		
			Bayer Environmental Science	PER	
			End use product is not potentially explosive.		
			Bayer Environmental Science	PER	
			End use product is not to be diluted with petroleum solvents.		
Signature <i>Patricia A. Sheehy</i>			Name and Title Patricia A. Sheehy Manager, Regulatory Affairs		Date October 31, 2011

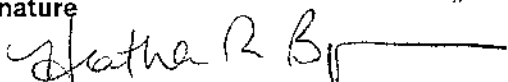
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 31, 2011			EPA Reg. No./File Symbol: 68451-1		Page 2 of 3
Applicant's/Registrant's Name & Address: Intervet Inc., 566 Morris Avenue, Summit, New Jersey 07901			Product: Deltamethrin 4% Collar		
Ingredient: Deltamethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer Environmental Science	PER	in progress
			End use product is not to be used around electrical equipment.		
			End use product is not to be dispersed with water.		
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
					Waiver Request
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Bayer Environmental Science	PER	
			Intervet Inc.	Own	Submitted 12/26/1996
			Intervet Inc.	Own	Submitted 6/10/1998
Signature 			Name and Title Patricia A. Sheehy, Manager, Regulatory Affairs		Date October 31, 2011

401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Page 3 of 3

Product: Deltamethrin 4% Collar

Ingredient: Deltamethrin

[illegible]

Letter RB

Patricia A. Sheehy, Manager, Regulatory Affairs

October 31, 2011

MATERIAL TO BE ADDED TO JACKET

REG #

68451-1

Description:

PR Notice 2007-4

Changes

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input type="checkbox"/>	new CSF
<input checked="" type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's

Name:

Banza Djapao

Date:

Phone:

703-305-7269

Division:

RD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 17 2009

Ms Heather R. Bjornson
Intervet Inc.
29160 Intervet Lane
Millsboro, DE 19966

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10
Storage & Disposal and other changes (Warranty Statement)

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated June 9, 2009 for:

EPA Registration 68451-1 Deltamethrin 4% Collar

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>JUL 17 2009</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Heather R. Bjornson, hbjornson@tsgusa.com	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 628-8945	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant to Intervet Inc.		
4. Typed Name Heather R. Bjornson	5. Date June 9, 2009		



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesco	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input checked="" type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 collar, 0.9 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, hbjornson@tsgusa.com	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant to Intervet Inc.	
4. Typed Name Heather R. Bjornson	5. Date July 7, 2009	



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

June 9, 2009

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

Notification per PR Notice 2007-4

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Ms. Nesci:

Technology Sciences Group, Inc., on behalf of Intervet Inc., submits the enclosed notification to update the label per PR Notice 2007-4 and to make additional minor text revisions. You will find the following in support of this notification:

- 1) Notification application form,
- 2) One redline version of the revised label, and
- 3) One clean version of the revised label.

Please do not hesitate to contact me with any questions and/or concerns.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

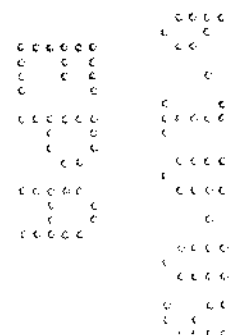
K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Sincerely,

Heather R. Bjornson
Regulatory Assistant to Intervet Inc.
Direct dial: (202) 828-8945
e-mail: hbjornson@tsgusa.com



This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

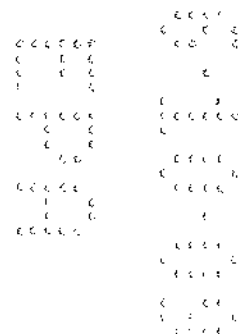
EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France



Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

June 4, 2009

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container of label with you when calling a poison control center or doctor, or going for treatment.	

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from

the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

NOTIFICATION

JUL 17 2009

Deltamethrin 4% Collar (EPA Reg. No. 68451-1)

June 4, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms Patricia A. Sheehy, MS
Intervet Inc.
56 Livingston Avenue, R-3-3153G
Roseland, New Jersey 07068

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10
Storage & Disposal and other changes

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated February 23, 2010 for:

EPA Registration 68451-1 Deltamethrin 4% Collar

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in cursive script that reads "Rachel C. Halloran".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

MATERIAL TO BE ADDED TO JACKET

REG #

68451-1

Description:

Notification for PRN 2007-4
Q 98-10

check all that apply		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input checked="" type="checkbox"/>	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's

Name:

BANZA DIAPAD

Date:

4-26-10

Phone:

305-7269

Division:

AA



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION APR 15 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Patricia A. Sheehy, M.S.		Title Manager, Regulatory Affairs		Telephone No. (Include Area Code) (852) 245-3551	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Gate Application Received (Stamped)
2. Signature 		3. Title Manager, Regulatory Affairs			
4. Typed Name Patricia A. Sheehy, M.S.		5. Date 2-23-2010			

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

NOTIFICATION

APR 15 2010

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes; then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

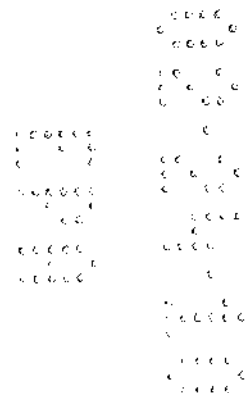
(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant



February 23, 2010

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -I)
Notification per PR Notices 98-10 and 2007-4**

Dear Ms. Nesci:

Following my conversation with Melody Banks this morning Intervet Inc has removed the statements previously submitted in our December 22, 2009 notification that do not fall within the scope of PR Notice 98-10 and PR Notice 2007-4 related to vector borne diseases. Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

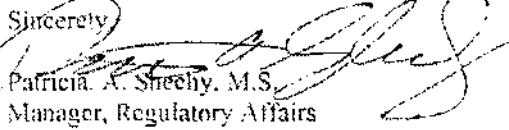
Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-2453551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely,


Patricia A. Sheehy, M.S.
Manager, Regulatory Affairs
enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION APR 13 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1-collar net wgt 0.9 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On carton	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other carton label - ink jet			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Patricia A. Sheehy, M.S.	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (862) 245-3551
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 		
ed Name Patricia A. Sheehy, M.S.	3. Title Manager, Regulatory Affairs	
5. Date 3-25-10 resubmission of application to 2-23-2010 Notification		



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION APR 15 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Ma Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Patricia A. Sheehy, M.S.	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (832) 245-3551	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped) _____
2. Signature 	3. Title Manager, Regulatory Affairs		
4. Typed Name Patricia A. Sheehy, M.S.	5. Date 2-23-2010		

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

NET CONTENTS: 1 Collar
NET WT. 10.9 oz

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar.

Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® Protector Band for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar.

Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

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(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant

February 23, 2010

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
US. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -1)
Notification per PR Notices 98-10 and 2007-4

Dear Ms. Nesci:

Following my conversation with Melody Banks this morning Intervet Inc has removed the statements previously submitted in our December 22, 2009 notification that do not fall within the scope of PR Notice 98-10 and PR Notice 2007-4 related to vector borne diseases. Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

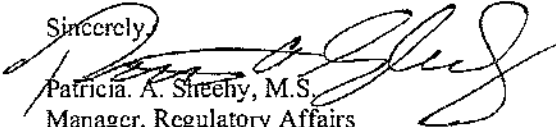
Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely,


Patricia A. Sheehy, M.S.
Manager, Regulatory Affairs
enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other - Explain below.

NOTIFICATION

APR 15 2010

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1-collar net wgt 0.9 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On carton	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other carton label - ink jet			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Patricia A. Sheehy, M.S.	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (862) 245-3551
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Printed Name Patricia A. Sheehy, M.S.	5. Date 3-25-10 resubmission of application Apr 2-23-2010 Notification	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION APR 15 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Patricia A. Sheehy, M.S.		Title Manager, Regulatory Affairs	
		Telephone No. (Include Area Code) (862) 245-3551	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Manager, Regulatory Affairs	
4. Typed Name Patricia A. Sheehy, M.S.		5. Date 2-23-2010	

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container of label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

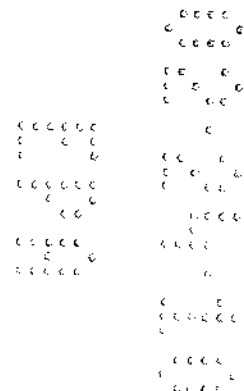
(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant



DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container of label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 4 of 4
revision date: 02-23-10

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

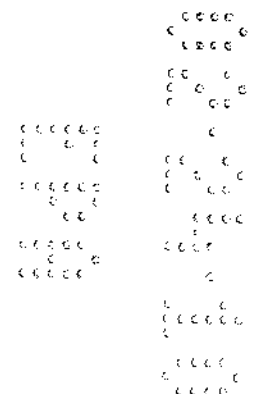
(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant



MATERIAL TO BE ADDED TO JACKET

REG #

68457-1

Description:

PRN 2007-4 / Rejection

check all that apply		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input checked="" type="checkbox"/>	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's
Name:

Melody Banks

Date:

2-17-10

Phone:

305-5413

Division:

PR



Decision Seq: 426587	Action Code: 332, NOTIFICATION, 30		...	Decision Status
FFS Start Date:	Tentative Ind: No	FFS Original Decision:	...	Tracking
Due Date: 22-Jan-2010	75-Day Due Date:	FFS EUP Decision:	...	Create Resubmission
OPP Target Due Dt:		FFS Primary Decision:	...	FFS Letters
Negotiated Due Dt:		Start/Stop Clock: FQPA Clock:		Waiver Documentation
Registrant:	id	Days Elapsed:		Action Code History
Response Due Date:				
Current Status: PENDING (21-Jan-2010)				

Decision Comments	Payment	Unmatched Payments	75 Day Letters
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date
Decision Ownership	Receipts	Data Package	Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
FFS 665916	Banks Melody	...	68451-1	22-Jan-2010 PENDING

Notification Amendment per PR Notice 2007-4

Navigation bar with arrows and a search icon.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Patricia A. Sheehy
Intervet Inc. Corporation
56 Livingston Avenue
Roseland, New Jersey 07068

FEB 16 2010

Subject: PR Notice 2007-4/Rejection
Deltamethrin 4% Collar
EPA Reg. Number: 68451-1
Letter Dated 12/22/09

Dear Ms. Sheehy:

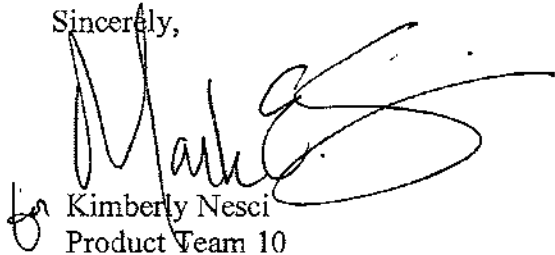
Your original request submitted to the Agency on December 22, 2009, as a Notification, did not clearly fall within the scope of PR Notice 98-10, 2007-4, and has been rejected.

The Optional/Alternate label text on page 4 of 4 requires product performance data to substantiate your propose labeling claims.

You may resubmit your application under an amendment with the appropriate data or data citations to substantiate these claims.

If you have any questions, please contact Melody Banks on 703 305-5413.

Sincerely,


for Kimberly Nesci
Product Team 10
Insecticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (include ZIP Code) Intervet Inc. Corporation 56 Livingston Avenue Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION FEB 16 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Patricia A. Sheehy, M.S.		Title Manager, Regulatory Affairs	
		Telephone No. (include Area Code) (862) 245-3551	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 12-23-09
2. Signature 		3. Title Manager, Regulatory Affairs	
4. Typed Name Patricia A. Sheehy, M.S.		5. Date 12-22-09 (revised 1-8-2010)	

December 22, 2009 (revised January 5, 2010)

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -1)
Notification per PR Notices 98-10 and 2007-4**

Dear Ms. Nesci:

Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

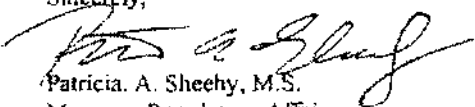
Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely,


Patricia A. Sheehy, M.S.
Manager, Regulatory Affairs
enclosures

**DELTAMETHRIN 4% COLLAR
FLEA & TICK COLLAR FOR DOGS**

NOTIFICATION

FEB 16 2010

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product if France

Universal Product Code Number (Bar Code)

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 4 of 4
revision date: 12-22-09

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

Kills ticks

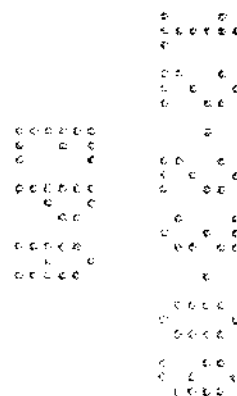
SCALIBOR® protector band the long lasting, easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant



**DELTAMETHRIN 4% COLLAR
FLEA & TICK COLLAR FOR DOGS**

NOTIFICATION
FEB 16 2010

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 - 20 minutes.• Call a poison control center or doctor for treatment advice.
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For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container of label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product of France

Universal Product Code Number (Bar Code)

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

SCALIBOR® Protector Band the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting collar easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant

Decision Seq: 427000	Action Code: 332,NOTIFICATION,30		Decision Status	
FFS Start Date:	Tentative Ind: No	FFS Original Decision:	Tracking	
Due Date: 22-Jan-2010	75-Day Due Date:	FFS EUP Decision:	Create Resubmission	
OPP Target Due Dt:		FFS Primary Decision:	FFS Letters	
Negotiated Due Dt:		Start/Stop Clock: FQPA Clock:	Action Code History	
Registrant		Days Elapsed:		
Response Due Date:				
Current Status: PENDING (28-Jan-2010)				
Decision Comments	Payment	Unmatched Payments	75 Day Letters	
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date	
Decision Ownership	Receipts	Data Package	Reduced Risk	
Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 866344	Banks, Melody	68451-1	22-Jan-2010	PENDING
Notification per PR Notice 98-10 and 2007-4				



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. Corporation 56 Livingston Avenue Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION FEB 16 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Patricia A. Sheehy, M.S.	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (852) 245-3551
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		5. Date Application Received (Stamped) 12-23-09
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Patricia A. Sheehy, M.S.	5. Date 12-22-09 (revised 1-8-2010)	

December 22, 2009 (revised January 5, 2010)

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**RE: Deltamethrin 4% Collar (EPA Reg. No. 68451-1)
Notification per PR Notices 98-10 and 2007-4**

Dear Ms. Nesci:

Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

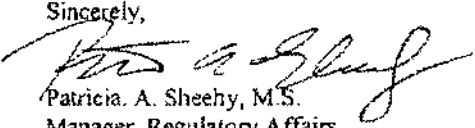
Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely,


Patricia A. Sheehy, M.S.
Manager, Regulatory Affairs
enclosures

**DELTAMETHRIN 4% COLLAR
FLEA & TICK COLLAR FOR DOGS**

NOTIFICATION

Alternate Brand Names:

FEB 16 2010

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

NET CONTENTS: 1 Collar
NET WT: 0.9 oz

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206	
For incidents involving ANIMALS , call 1-800-548-2423	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. XXXXX
Product of France

Universal Product Code Number (Bar Code)

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 4 of 4
revision date: 12-22-09

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

Kills ticks

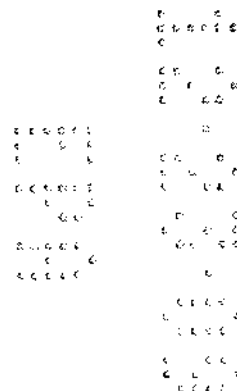
SCALIBOR® protector band the long lasting, easy to use vector borne disease protection for dogs

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant



**DELTAMETHRIN 4% COLLAR
FLEA & TICK COLLAR FOR DOGS**

NOTIFICATION

FEB 16 2010

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable – One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-548-2423 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

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Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

SCALIBOR® Protector Band the long lasting, easy to use vector borne disease protection for dogs

(Deltamethrin 4% Collar) (alternate brand name) the long lasting, easy to use vector borne disease protection for dogs

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